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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,073	04/20/2001	Todd C. Sacktor	13492	2721
<div>7590      09/21/2007</div> <div>Leopold Presser, Esq. SCULLY, SCOTT, MURPHY &amp; PRESSER 400 Garden City Plaza Garden City, NY 11530</div> <div>EXAMINER PAK, MICHAEL D</div> <div>ART UNIT      PAPER NUMBER</div> <div>1646</div> <div>MAIL DATE      DELIVERY MODE</div> <div>09/21/2007      PAPER</div>				

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/839,073	<b>Applicant(s)</b> SACKTOR, TODD C.	
	<b>Examiner</b> Michael Pak	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11, 13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 13, 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 9, 2007 has been entered.

### ***Response to Amendment***

2. Claims 11, 13, and 15 are examined below. Claims 1-10, 12 and 14 have been cancelled.
3. Applicant's arguments filed July 9, 2007, have been fully considered but they are not found persuasive.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 11 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Ghosh et al. (US 6,268,398) with evidence by Lang et al. (US 2005/0064501).

Ghosh et al. teach the method of administering chelerythrine as kinase inhibitors for therapy of many diseases including Alzheimer's disease, diabetes mellitus, neuropathy, epilepsy, stroke and traumatic injury to the brain (columns 2, 4, 6, 17-20, and 22)

The patients with the above listed diseases would have the pain syndrome as well associated with the diseases. The administration of Chlerythrine inherently has the amnesiac effect. Lang et al. teach that the chlerythrine suppresses the activation of the Na<sup>+</sup> channel (page 1, paragraph 0023, 0052-0057). Lang et al. teach treatment of epileptic seizure with kinase inhibitors (page 2, paragraph 0028). Lang et al. teach diagnosing of epilepsy, hypertension, fibrosing pancreatitis, radiation fibrosis,

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scleroderma, cystic fibrosis, chronic bronchitis using tissues of brain, Alzheimer's disease, cirrhosis of the liver, Crohn's disease, fibrosing pancreatitis and pulmonary fibrosis, arteriosclerosis, diabetic nephropathy.

Applicants argue that Ghosh et al. is directed to compositions and methods for treatment of certain mitochondrial-associated diseases and Ghosh et al. does not disclose a method of causing amnesia. However, as discussed above the claims are drawn to a method of decreasing synaptic transmission in the alternative which is taught by Ghosh et al. as suppression of activation of Na<sup>+</sup> channel by Chlerythrine.

Furthermore, Chlerythrine inherently has the amnesiac effect when administered to treat diseases such as epileptic seizure. Whether Ghosh et al. describes the disease as mitochondrial-associated is not as important as the fact that Ghosh et al. administers Chlerythrine into epileptic patients which inherently results in the preamble stated effect. It should be noted that the method steps only require the administration of the PKM $\zeta$  inhibitor. Furthermore, Chlerythrine will inherently inhibit PKM $\zeta$ .

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 11, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Thiam et al.(FEBS Letter, 1999) with evidence by Lang et al. (US 2005/0064501).

The teachings of Ghosh et al. with evidence of Lang et al. has been set forth above. Ghosh et al. does not teach the myristoylation pseudosubstrate peptide.

Thiam et al teach the method of administering palmitoylated modified PCK- $\zeta$  pseudosubstrate lipopeptides on HL60 human cells (page 286 and figures 1-3). The claims method step requires administration of a therapeutically effective amount which is met by concentration of 10 uM (page 287-288). The palmitoylated peptide is a subgenus of myristoylation peptide meeting the claim limitation of claim 13.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ghosh et al. by substituting the myristolated pseudosubstrate peptide of Thiam et al. One of ordinary skill in the art would have been motivated to modify the method of Ghosh et al. because Ghosh et al. explicitly consider chelerythrine, Staurosporine or other kinase inhibitors and pseudosubstrate peptide of

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Thiam et al. is a kinase inhibitor. Furthermore, one of ordinary skill in the art would have been motivated because Thiam et al. is an analogous art with Lang et al. because both use kinase inhibitors.

Applicants argue that Thiam et al. do not teach a method of causing amnesia or decreasing synaptic transmission by administering a therapeutically effective amount of of a PKM- $\zeta$  inhibitor. However, the combination of Ghosh et al. in view of Thiam et al. teach the administration of the pseudosubstrate peptide which would inherently decrease the synaptic transmission. One of ordinary skill in the art would have been motivated to modify the method of Ghosh et al. because Ghosh et al. explicitly consider chelerythrine, Staurosporine or other kinase inhibitors and pseudosubstrate peptide of Thiam et al. is a kinase inhibitor. Furthermore, one of ordinary skill in the art would have been motivated because Thiam et al. is an analogous art with Lang et al. because both use kinase inhibitors.

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Michael D. Pak*

Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
14 September 2007